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Kozmetika - Smernice za preskušanje stabilnosti kozmetičnih izdelkov

Cosmetics - Guidelines on the stability testing of cosmetic products

Cosmétiques - Lignes directrices relatives aux essais de stabilité des produits cosmétiques

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Cosmetics — Guidelines on the stability testing of cosmetic products

Cosmétiques — Lignes directrices relatives aux essais de stabilité des produits cosmétiques

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Foreword

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This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Introduction

Stability studies are aimed at assessing the ability of a product to maintain the desired physical, chemical and microbiological properties, as well as functionality and sensorial properties when stored and used under appropriate conditions by the consumer. More simply, the objective of a stability study is to determine the shelf life of a product and to evaluate whether a product in the package is stable when subjected to the market conditions in which it is sold and used. The "market conditions" encompass distribution (transportation), warehouse storage and conditions during use.

Thus, the stability study may be seen as a prerequisite for ensuring product quality. Stability tests on cosmetic products are required for

— obtaining a guidance on the formulation of the product, and the appropriate packaging material,

— optimizing the formulation and manufacturing process,

— determining conditions of transportation, storage, display and manner of use,

— estimating and confirming shelf life, and

— ensuring customer safety.

This document identifies readily available references to assess the stability of cosmetic products on the market. Its purpose is to provide a resource for the selection of the appropriate stability tests. Although these guidelines provide a helpful starting point to evaluate new products and technologies, adapting the testing to reflect differences between product types and formulations may still be necessary.

Cosmetics — Guidelines on the stability testing of cosmetic products

1 Scope

This document gives guidelines for the stability testing of cosmetic products. It reviews readily available bibliographic references that provide a resource for the assessment of the stability of cosmetic products. This review of the available guidelines that assess the stability of cosmetic products can serve as a technical/scientific framework to identify the most suitable methods for the assessment of the stability of cosmetic products.

This document does not aim to specify the conditions, parameters or criteria of stability testing.

Considering the wide variety of cosmetic products, storage and use conditions, it is not possible to define a single way to assess product stability. Therefore, it is up to the manufacturer to specify and justify the stability protocol to cover test methods, specifications and conditions at which products will be tested.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
accelerated stability evaluation
study designed to speed up naturally occurring destabilization processes due to intrinsic or extrinsic factors and which predicts the behaviour over the long term

Note 1 to entry: Typically, physico-chemical, mechanical or thermal procedures are employed.

3.2
real time stability evaluation
study that monitors the state of a product to determine the time course of any alteration to it under reasonably expected conditions of storage and use

Note 1 to entry: Often called “long term test” or “standard stability test”.

3.3
stability
ability of a cosmetic product to resist change or variation of its initial properties over time under stated or reasonably foreseeable conditions of storage and use

Note 1 to entry: See Reference [1].

3.4
stability criteria
deviations from initial properties or behaviour at production state, which are acceptable

Note 1 to entry: See Reference [1].

3.5
stability metrics
properties/parameters of the state or behaviour of a cosmetic product which should be monitored according to demanded, specific product qualities

Note 1 to entry: See Reference [1].

3.6
shelf life
recommended time period that a cosmetic product can be kept after its production, during which the defined quality of the product remains acceptable under expected conditions of distribution, storage, display and usage

Note 1 to entry: See Reference [1].

4 Basic principles of cosmetic stability

Design, formulation and the manufacturing process of cosmetic products have to fulfil general and specific demands and requirements of distribution pathways, and especially of customers. Specification, functionality and aesthetics have to be preserved, i.e. have to be stable, over the entire life cycle of a product.

Processed cosmetic products are complex matrixes which undergo spontaneous alterations to reach the free energy minimum in accordance with the second thermodynamic law.[2] These so-called intrinsic causes may be of physical, physico-chemical or chemical origin.[3] Many reactions and processes may lead, under the condition of the "market" to a deviation from the initial, original product properties at the date of manufacturing. Departure may be caused by thermodynamically driven internal or externally driven effects,[1] microbiological impact[4][5] or interactions with packaging[6] and may finally lead to a loss of specified product functionality or/and aesthetic attributes. This impacts usability, shelf life and marketability. Destabilization processes of the original product may also be provoked, enhanced or magnified due to extrinsic (external) factors. For example, state changes may be triggered by thermal energy loss or gain, light and UV irradiation, mechanical energy input (such as vibration or pressure), oxygen uptake, humidity, interaction by or with container/closure system (packaging), and proliferation of microorganisms.[3]

Cosmetics are of different natures and some consist of several phases, dispersed ones and a continuous one, and may be classified as suspensions or emulsions. Suspensions are solid particles dispersed in a liquid phase. Emulsions are composed of two liquid phases, typically oil-in-water (o/w) or water-in-oil (w/o). Cosmetic dispersions are usually very complex and may contain several phases.

A stability test aims at providing information on the state/behaviour of the cosmetic products in the container/enclosure under the different conditions to which they may be subjected from their manufacturing date until the end of their recommended period of use.[7][8][9] The state of a cosmetic product and its stability depend upon numerous interrelated physical, physico-chemical and chemical parameters as well as interaction with environment, and its nature is therefore very complex. In general, they may be roughly classified as mechanical-driven, thermal- or diffusion-driven, interaction-force- driven or externally provoked processes.[1][7][10][11] There is no universal method or technique to quantify all stability aspects due to the complexity of different pathways of destabilization. Therefore, it is always necessary to specify precise stability metrics and acceptance criteria.

After determination of the stability metric(s), it is necessary to select appropriate stability test methods to monitor the alteration of the product over time. It is recommended to select methods that do not require sample preparation (e.g. dilution) and quantify kinetics of the product destabilization based on defined metric(s) in a direct way.[1] Real time measurements can be made by traditional visual

observations, sensory techniques or use of different measuring techniques which are advantageous in being quantitative, objective, traceable, reproducible and retrievable.[1] Scanning and spatially resolving techniques are appropriate in particular to detect phase separation and help to discriminate between phase separation and phase changes.[1][7][10][11]

In the case of very stable products, analytical techniques having high resolution/sensitivity should be used and procedures can be required in order to accelerate the alteration to shorten the detection time to meet the predefined stability criteria.[1][11] Typical acceleration approaches are mechanical ones (e.g. high gravity by centrifugation) or elevated storage temperatures for a given time. Preservation efficacy testing (challenge-test) aims to test microbiological attributes under accelerated conditions.[3][5] However, because of the interrelated physical, physico-chemical and chemical properties of cosmetic emulsions or suspensions, adequate acceleration methods may be chosen and verified in the context of a specific product.[1][11]

Beside direct methods, correlative test methods are utilized focusing on determination of a single parameter of the state of a product that is known to correlate with product stability.[1] Typical parameters measured and compared with pre-defined acceptable values are, for example, mean particle/droplet size or zeta-potential. These quantities reflect the state at the time of the measurement and do not yield kinetic information. Such test procedures may be used for quality assessment of a specified product but, due to the complexity of the state of cosmetic products, currently no theoretical basis exists to predict the time course of any product alteration based on a single parameter obtained at any single time point. In addition, most of these measuring techniques demand sample preparation and often product dilution.[1]

Due to the cosmetic product formulation's complexity overall, caution should be employed in stability assessment and predicting its shelf life, and the properties of the constituents should be considered and understood, as well as the product's behaviour and the factors which influence it.[11]

5 Aspects to be addressed during stability testing

5.1 General

The key aspects to consider when assessing the stability of cosmetics products are listed in 5.2 to 5.6. Guidance is provided based on the review of relevant sources cited in the text.

5.2 Stage/scale of tested batches

When working on a brand new product (new formula, new manufacturing process, new packaging) and therefore where no significant body of knowledge is available, it might be appropriate to carry multiple independent stability studies, usually referred as "preliminary tests". It is up to the manufacturer to decide on the number of batches, the scale of their manufacture that are subject to stability testing and at what stage of the project development cycle this takes place.[7][12][9][13]

The stability of the final product (final formula, final manufacturing process, final packaging) may be demonstrated before its commercialization. Accelerated stability evaluation may be conducted prior to commercialization to predict product shelf life. Following commercialization, the shelf life confirmation is obtained by long term stability testing on representative formulations.

Minor variations between products subjected to stability testing versus final commercial product can be acceptable if they are deemed as not having an impact on product characteristics and integrity, but need to be documented and justified.[9]

Common acceptable practices include but are not limited to

— usage of formulation samples from the development stage for preliminary tests,

— usage of pilot batches instead of production scale, for some specific non-scale up products and where the manufacturing process is considered equivalent,[13][14] and